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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,903	01/16/2002	Robert H. Zimmer	945505.0019	5841

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EXAMINER

TELLER, ROY R

ART UNIT PAPER NUMBER

1654

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/050,903	ZIMMER, ROBERT H.	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 23-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-22 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>06182003</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This office action is in response to the election, received 10/29/03, in which applicant elected group I, claims 1-22 without traverse.

Claims 1-22 are pending.

Information Disclosure Statement

The information disclosure statement, received 6/18/03, is acknowledged. A signed copy is attached hereto.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 4-22 are rejected under 35 U.S.C. 112, first paragraph, because while the instant application has reasonably disclosed and/or demonstrated a carrier to a peptide, as recited from the group in claim 3, the claims encompass any carrier and any protein. This is beyond the scope of the present invention and would constitute undue experimentation to one of skill in the art to prepare a peptide-carrier moiety which provides stability, function, and the effects instantly disclosed, other than a therapeutically active peptide in

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which the carrier moiety is selected from those recited in claim 3.

In addition, claims 9-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a carrier moiety and a therapeutically active peptide species as set forth above does not reasonably provide enablement for a linker species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

With regard to the enablement rejection above, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

1) the nature of the invention;

The instant invention is drawn to a pharmaceutical agent comprising a carrier moiety; a therapeutically active peptide species; and a linker species.

2) the amount of direction or guidance presented;

The instant application provides guidance in the use of a carrier moiety and a therapeutically active peptide species.

3) the presence or absence of working examples;

The instant application provides a working example of a carrier moiety, cinnamoyl, and a therapeutically active peptide species, met-enkephalin, but no working example is provided for a carrier moiety, a therapeutically active peptide species, and a linker

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species.

- 4) the quantity of experimentation necessary;

The amount of experimentation necessary is considered undue.

In consideration of each of the factors, it is apparent that there is undue experimentation because variability in prediction of outcome that is not addressed by present application disclosure, examples, teaching, and guidance presented. Absent factual data to the contrary, the amount of experimentation needed is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 recites the limitation "the method" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is unclear what the method is as claim 1 is drawn to a product.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the linker species is Gly-carba-Gly, a pseudo-peptide, this is vague and indefinite because it is unclear what carba is.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-7, and 16-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Li, USPN 6,136,952.

The instant invention is drawn to a pharmaceutical agent comprising a carrier moiety and a therapeutically active peptide species.

Li teaches various molecules can be attached to a JAGGED polypeptide including, for example, other polypeptides or chemical moieties, see column 8, lines 24-26. Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-7, and 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li, USPN 6,136,952 in view of Lipton, PG PUB 20020090603.

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The instant invention is drawn to a pharmaceutical agent comprising a carrier moiety and a therapeutically active peptide species.

Li beneficially teaches various molecules can be attached to a JAGGED polypeptide including, for example, other polypeptides or chemical moieties, see column 8, lines 24-26.

Lipton also beneficially teaches teaches various molecules can be attached to a MEF2 polypeptide, for example, other polypeptides, carbohydrates, lipids, or chemical moieties, see paragraph 77, lines 8-9.

It would have been obvious to prepare various types of peptide-carrier moiety formulation based upon the beneficial teachings provided by the cited references, as discussed above.

The result-effective adjustment of particular conventional working conditions (e.g., incorporating one of various types of therapeutic peptides therein and/or formulating such peptides-carrier for a particular route of administration such as oral, parenteral, intravenous, etc.) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

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Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703)305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703)306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

RT
1654
1/9/04

RT



CHRISTOPHER R. TATE
PRIMARY EXAMINER